

FEDERAL S&C

NEW ENGLAND COMPOUNDING PHARMACY,
INC.
DBA NEW ENGLAND COMPOUNDING
C/O GREGORY CONIGLIARO, REGISTERED
AGENT
697 WAVERLY STREET, FRAMINGHAM, MA

AO 440 (Rev. 02/09) (12/09 WD/VA) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of Virginia

A TRUE COPY ATTEST
DAVID D. AYLES, PROCESS SERVER
AND DISINTERESTED PERSON

Sharon G. Wingate, Executor of The Estate of
Douglas Gray Wingate, deceased

Plaintiff

v.

New England Compounding PHarmacy, Inc. d/b/a
New England Compounding Center, et al.

Defendant

Civil Action No.

7:12-CV-576

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center
Gregory Conigliaro, Registered Agent
697 Waverly Street
Framingham, MA 01701

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — or 120 days for Social Security Cases filed pursuant to 42 USC 405(g) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

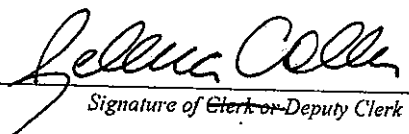
J. Scott Sexton, Esq.
Gentry Locke Rakes & Moore, LLP
10 Franklin Road, SE, Suite 800
Roanoke, Virginia 24011

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date:

11-26-12


Signature of Clerk or Deputy Clerk

AO 440 (Rev. 02/09) (12/09 WD/VA) Summons in a Civil Action (Page 2)

Civil Action No. _____

PROOF OF SERVICE*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* _____
 was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____
 _____ on *(date)* _____; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____
 _____, a person of suitable age and discretion who resides there,
 on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is
 designated by law to accept service of process on behalf of *(name of organization)* _____
 _____ on *(date)* _____; or

☐ I returned the summons unexecuted because _____; or

☐ Other *(specify)*: _____

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ROANOKE DIVISION

SHARON G. WINGATE, EXECUTOR OF
THE ESTATE OF DOUGLAS GRAY
WINGATE, DECEASED,

Plaintiff,

v.

Civil Action No.: _____

NEW ENGLAND COMPOUNDING
PHARMACY, INC. D/B/A NEW ENGLAND
COMPOUNDING CENTER

Serve: Gregory Conigliaro, Its Registered Agent
697 Waverly Street
Framingham, MA 01701,

MEDICAL SALES MANAGEMENT, INC.

Serve: Gregory Conigliaro, Its Registered Agent
697 Waverly Street
Framingham, MA 01701,

and

BARRY J. CADDEN,
Serve at: 13 Manchester Drive
Wrentham, MA 02093

Defendants.

COMPLAINT

Sharon G. Wingate, Executor of the Estate of Douglas Gray Wingate, deceased, by counsel, states this Complaint against New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"), Medical Sales Management, Inc. ("MSM"), and Barry J. Cadden ("Cadden") (hereinafter collectively referred to as the "defendants"):

Preliminary Statement

1. This lawsuit arises from the untimely death of Douglas Gray Wingate ("Mr.

Wingate"). To more fully enjoy the 25th wedding anniversary trip he had planned with his wife, Mr. Wingate received a medically prescribed epidural steroid injection in his neck on September 6, 2012. Being in otherwise very good health, the purpose of the injection was to relieve shoulder pain associated with narrowing (stenosis) in his cervical spine. He died 12 days later at the age of 47 because the steroid shot, manufactured, advertised and distributed by the defendants, was adulterated and contaminated with fungus or mold bearing pathogens that were injected into his central nervous system along with the immune system suppressing steroid. As the fungus grew inside Mr. Wingate's spinal fluid, he developed fungal meningitis, severely inflaming the tissues lining his brain and spinal cord. Ultimately, the pressure created inside Mr. Wingate's skull led to deep brain strokes, seizures and, ultimately, death. He left behind a wife and two teenage children as statutory beneficiaries. This lawsuit seeks compensation from the defendants for Mr. Wingate's death.

Parties

2. On September 18, 2012, Mr. Wingate died as a result of brain damage and other complications associated with fungal meningitis.

3. On October 5, 2012, Mr. Wingate's wife, Sharon G. Wingate ("Mrs. Wingate" or the "Executor") duly qualified as the Executor of Mr. Wingate's Estate in the Commonwealth of Virginia.

4. Mr. Wingate was a citizen of the Commonwealth of Virginia.

5. NECC is a Massachusetts corporation that maintains its principal place of operations at 697 Waverly Street, in Framingham, Massachusetts.

6. MSM is a Massachusetts corporation that maintains its principal place of operations at 701 Waverly Street, Framingham, Massachusetts.

7. Cadden, who was at all relevant times the responsible pharmacist for NECC, is a Massachusetts resident.

Jurisdiction and Venue

8. This matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

9. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a).

10. A substantial part of the events or omissions giving rise to this claim occurred in this judicial district.

11. Venue is proper in this Court pursuant to at least 28 U.S.C. § 1391(b)(2).

Factual Background

The Defendants' Operations

12. NECC is jointly owned by Cadden, his wife, Lisa Cadden and her brother, Gregory Conigliaro.

13. The defendants operated a compounding pharmacy in Framingham, Massachusetts.

14. Compounding pharmacies engage in mixing (or "compounding") drug products for specific patients, pursuant to a valid prescription.

15. Because they typically compound drug products in forms that are not commercially available, compounding pharmacies are not regulated by the FDA.

16. Rather, compounding pharmacies are generally regulated under state law applicable to pharmacies and pharmacists. Although it operates in Massachusetts, NECC must also comply with Virginia law in order to fill prescriptions in Virginia. It must be licensed and registered with the Virginia Board of Pharmacy.

17. MSM is a separate corporate entity from NECC. Upon information and belief, at all relevant times, MSM served as the marketing arm for New England Compounding, providing marketing and advertising services, promoting the compounding business at medical trade shows nationwide, “cold-calling” potential customers, calling existing customers, and managing NECC’s online operations.

18. Cadden is the pharmacist in charge of NECC’s operations, and was listed as such in NECC’s registration as a nonresident pharmacy in Virginia.

19. As pharmacist in charge, Cadden was at all relevant times personally responsible to ensure that NECC’s operations complied with Virginia laws. Va. Code § 54.1-3434.1 (any non-resident pharmacy “*shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter . . .*” (emphasis added).

20. Furthermore, as pharmacist in charge of NECC, Cadden was at all times personally responsible to supervise NECC’s operations at its facility in Framingham, Massachusetts. Va. Code § 54.1-3432 (“Every pharmacy shall be under the *personal supervision* of a pharmacist on the premises of the pharmacy.”) (emphasis added).

21. The defendants are in the business of compounding and manufacturing medications and drugs, including methylprednisolone acetate. The brand name of this drug, Depo-Medrol, is produced by the FDA-regulated company, Pharmacia & Upjohn Company, a Division of Pfizer, Inc. Other FDA-regulated drug manufacturers produce generic versions of this drug.

22. Rather than producing small quantities of this knock-off Depo-Medrol, NECC produced vast batches of this drug, thousands at a time. It then acted as a wholesale distributor.

23. The defendants compounded and manufactured medications, including methylprednisolone acetate, that were contaminated with fungus, mold and other contaminants.

24. Under Virginia Code §54.1-3435.01(A), non-resident pharmacies that engage in wholesale distribution of prescription drugs into the Commonwealth of Virginia must register with the Virginia Board of Pharmacy, in addition to registering as a non-resident pharmacy.

25. NECC is and was registered in the Commonwealth of Virginia as a non-resident pharmacy, but is not and was not registered as a wholesale distributor of prescription drugs as required by Virginia Code §54.1-3435.01(A).

26. Under Virginia law, the compounding pharmacist must ensure compliance with USP-NF standards (United States Pharmacopeial National Formulary). Virginia Code § 54.1-3410.2(E).

27. Pharmacists and pharmacies may not engage in “the regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products.” Virginia Code § 54.1-3410.2(H)(2).

28. As well as other drugs, the defendants produced methylprednisolone acetate without preservative, which they then sold to clinics, hospitals and other healthcare providers in bulk, packaging the drug in single dosage vials.

29. Such large-scale production of a commercially available drug is illegal under Virginia Code § 54.1-3410.2(H)(2).

30. NECC is not accredited by the Pharmacy Compounding Accreditation Board (“PCAB”) or any other similar organization, such as The Joint Commission, that offers independent assurance as to the quality and competence of compounding pharmacies that meet certain requirements.

31. The drug at issue was to be used in epidural steroid injections allowing direct contact with the central nervous system. It was produced from non-sterile ingredients which then had to be

rendered sterile as a finished product, thus making the methylprednisolone acetate a high-risk compound. It was also produced without preservatives. Thus, although all drugs should be produced in a highly sterile environment, these drugs in particular must be. Additionally, sterilization techniques and sterility testing are crucial to properly producing such drugs.

32. However, the defendants purposefully maintained the supposedly sterile NECC pharmacy in an aged building that is surrounded by a waste recycling center owned by one of the co-owners of NECC, Gregory Conigliaro. This facility, called Conigliaro Enterprises, receives many varieties of garbage and waste which are sorted, stored, and manipulated just outside the back door of the NECC facility. A photograph showing the rear wall and backyard of the "pharmacy" is attached as **Exhibit A**.

33. It is difficult to distinguish where NECC ends and the waste recycling center begins, if there is such a distinction in fact; but, the waste facility lists its address as 701 Waverly Street, Framingham, Massachusetts, and operates under the name "Conigliaro Industries." NECC lists its address as 697 Waverly Street. MSM lists its address as 701 Waverly Street, the same as Conigliaro Industries.

34. The conditions in which the defendants produced their products were unsanitary and unsterile. NECC failed to meet basic quality and sterility standards; and it failed to properly test the drugs at issue for sterility prior to releasing them. As a result, thousands of adulterated products manufactured by NECC were then released into the stream of commerce throughout the United States of America, including at least two clinics in the Commonwealth of Virginia.

35. The drug at issue in this case is a steroid which the defendants knew would be injected into patients so as to enter or potentially enter the central nervous system. The defendants also knew that such steroids act as immune-suppressing agents, thus weakening the patient's natural

ability fight off pathogens that could possibly be included in the injection. The defendants also knew that the central nervous system is a relatively closed system, making treatment options more difficult in the event of an adulterated invasion. Notwithstanding this knowledge, the defendants chose to operate NECC's facility in the same complex as the waste facility, chose to produce such drugs in bulk batches (making mistakes more likely), chose not to properly sterilize the drugs, and chose not to have the drugs sufficiently tested by an FDA-approved testing facility before release for sale.

Mr. Wingate's Medical Timeline and Death

36. Mr. Wingate and his wife, Sharon, planned a cruise to celebrate their 25th wedding anniversary. In order to more fully enjoy this special trip, Mr. Wingate spoke to his doctor about relieving the pain in his shoulder caused by a narrowing of his spine in the region of his neck (cervical).

37. Mr. Wingate was referred by his family practice physician for an epidural steroid injection. The typical method for receiving such an injection requires radiological facilities that allow the proper placement of the shot in exactly the right place with the assistance of equipment such as a fluoroscope. An anesthesiologist or an interventional radiologist usually performs such a procedure.

38. The first facility to which his doctor referred him could not provide the shot in time for the planned anniversary cruise, so Mr. Wingate obtained an appointment at Insight Imaging - Roanoke, a clinic in Roanoke, Virginia, to receive the epidural steroid injection that would alleviate his pain.

39. Mr. Wingate received the injection at the clinic on September 6, 2012.

40. Within days of the injection, Mr. Wingate began suffering headaches.

41. By September 11, 2012, Mr. Wingate was confined to bed with a painful headache.

42. On September 12, 2012, on the insistence of his wife, Mr. Wingate was taken to the emergency room at LewisGale Medical Center.

43. Upon taking his medical history and learning his symptoms, the emergency room medical staff tested for and confirmed he suffered from meningitis. Mr. Wingate was admitted to the hospital and given antibiotics intravenously for the meningitis.

44. By September 14, 2012, Mr. Wingate's symptoms had worsened; he was experiencing increasing sensitivity to light and noise.

45. In the evening of September 14, 2012, Mr. Wingate suffered a series of strokes and was unresponsive; he was placed in the Intensive Care Unit.

46. On Sunday, September 16, 2012, Mr. Wingate was confused but able to communicate to his wife. However, he then experienced more strokes and seizures in the evening, leaving him unresponsive. His brain activity ceased.

47. Mr. Wingate died on September 18, 2012 when he was removed from life support.

48. The medical examiner has since confirmed that the cause of Mr. Wingate's death was fungal meningitis.

49. Mr. Wingate's fungal meningitis was a direct and proximate result of having methylprednisolone acetate made by the defendants and contaminated with fungus, mold and other contaminants injected into his central nervous system.

50. Mr. Wingate's death occurred as a direct and proximate result of having methylprednisolone acetate made by the defendants and contaminated with fungus, mold and other contaminants injected into his body.

51. As a proximate result of the defendants' actions, Mr. Wingate's beneficiaries have suffered extreme mental anguish, sorrow, loss of companionship, comfort, guidance, kindly offices, invaluable services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes. Code Ann. § 8.01-50, et seq.

COUNT I: NEGLIGENCE PER SE

52. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

53. Virginia Code Section 8.01-221 establishes that a person who is harmed by violation of a statute may recover for such harm.

54. Virginia law also establishes that:

. . . the violation of a statute or municipal ordinance adopted for public safety constitutes negligence because the violation is the failure to abide by a particular standard of care prescribed by a legislative body. A party relying on negligence *per se* does not need to establish common law negligence provided the proponent of the doctrine produces evidence supporting a determination that the opposing party violated a statute enacted for public safety, that the proponent belongs to the class of persons for whose benefit the statute was enacted and the harm suffered was of the type against which the statute was designed to protect, and that the statutory violation was a proximate cause of the injury. Halterman v. Radisson Hotel Corp., 259 Va. 171, 176-77, 523 S.E. 2d 823, 825 (2000); Virginia Elec. & Power Co. v. Savoy Constr. Co., 224 Va. 36, 45, 294 S.E. 2d 811, 817 (1982)

Schlimmer v. Poverty Hunt Club, 268 Va. 74, 78-79, 597 S.E.2d 43, 46 (2004) (quotations omitted).

55. Virginia Code Sections 54.1-3400 et seq. (collectively known as "The Drug Control Act") are statutes enacted for public safety, in that they protect the public from the release of substandard and otherwise unreasonably dangerous pharmaceutical drugs and medications into the stream of Virginia commerce.

56. As a Virginia resident and consumer of a drug regulated by the Virginia Drug Control Act, Mr. Wingate belonged to the class of persons for whose benefit those statutes were enacted.

57. A drug is deemed adulterated under Virginia law if it has been produced, prepared, packed, or held under insanitary conditions whereby it has been rendered injurious to health. Va. Code §54.1-3461(A)(2).

58. Additionally, a drug is considered adulterated if it purports to be a drug recognized in an official compendium, but fails to meet the quality or purity standards set forth in the compendium or the federal act. Va. Code §54.1-3461(B).

59. By manufacturing and selling an adulterated drug into the stream of Virginia commerce, the defendants violated Virginia Code §§ 54.1-3457(1), which is part of the Virginia Drug Control Act.

60. By negligently adulterating a drug, the defendants violated Virginia Code §§ 54.1-3457(2), which is part of the Virginia Drug Control Act.

61. By failing to adhere to proper quality control standards in producing the drug given to Mr. Wingate, the defendants failed to comply with USP-NF standards in violation of Virginia Code § 54.1-3410.2(E).

62. By engaging in the wholesale distribution of prescription drugs in this Commonwealth without a valid unrevoked license to do so issued by the Virginia Board of Pharmacy, the defendants violated Virginia Code § 54.1-3435, which is part of the Virginia Drug Control Act.

63. As pharmacist in charge, defendant Cadden was personally responsible for ensuring that NECC did not violate the provisions of the Virginia Drug Control Act. (Va. Code § 54.1-3432).

64. The defendants' actions violating Va. Code §§ 54.1-3457(1) and (2), 54.1-3410.2(E), and 54.1-3435 proximately caused Mr. Wingate's death. He died as a direct and proximate result of having the defendants' adulterated drug containing a fungal pathogen injected directly into his central nervous system.

65. Death or injury of a patient resulting from consumption of or contact with adulterated drugs belongs to the category of harms against which the Virginia Drug Control Act was designed to protect.

66. Death or injury of a patient resulting from consumption of or contact with adulterated drugs distributed wholesale by an entity engaging in the wholesale distribution of prescription drugs in this Commonwealth without registration belongs to the category of harms against which Virginia Drug Control Act was designed to protect

67. United States Code §§ 21 U.S.C. 301 *et seq.* (collectively known as "The Federal Food, Drug and Cosmetic Act" or "FDCA") are statutes enacted for public safety, in that they protect the public from the release of adulterated, substandard and otherwise unreasonably dangerous pharmaceutical drugs and medications into the stream of U.S. Commerce:

68. Therefore, because the defendants violated each of the above statutes, Virginia Code § 54.1-3457(1), Virginia Code § 54.1-3457(2) and Virginia Code § 54.1-3435), the defendants' actions and inactions constitute negligence *per se*, and the plaintiff is entitled to recovery of funeral, burial, and medical expenses, as well as damages for the statutory beneficiaries' extreme mental anguish,

sorrow, loss of companionship, comfort, guidance, kindly offices, invaluable services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes.

COUNT II: NEGLIGENT MANUFACTURE

69. Plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

70. The defendants owed a duty to Mr. Wingate, all other foreseeable users of their products, and the public in general to timely and properly:

- a. operate in a clean and sterile environment with properly functioning equipment;
- b. establish quality control measures;
- c. implement quality control measures;
- d. manufacture uncontaminated products;
- e. obtain representative sterility testing for their products for contamination prior to releasing the products into the stream of commerce; and
- f. refrain from releasing contaminated products into the stream of commerce;
- g. refrain from operating their facility in immediate proximity to a waste recycling center owned and operated by one of NECC's co-owners, and thus causing an inordinately high possibility that their drugs would become contaminated by contact with spores or other contaminants contained in the waste recycling center;
- h. refrain from producing such a high quantity of drugs that implementing proper quality control measures became difficult or impossible; and
- i. refrain from engaging in any other act or omission determined during the course of discovery.

71. The defendants breached the above duties and acted negligently, in at least the following ways, by failing to timely and properly:

- a. operate in a clean and sterile environment with properly functioning equipment;
- b. establish quality control measures;

- c. implement quality control measures;
- d. manufacture uncontaminated products;
- e. quality test their products for contamination prior to releasing the products into the stream of commerce;
- f. refrain from releasing contaminated products into the stream of commerce;
- g. refrain from operating their facility in immediate proximity to a waste recycling center owned and operated by one of NECC's co-owners, and thus causing an inordinately high possibility that their drugs would become contaminated by contact with spores or other contaminants contained in the waste recycling center;
- h. refrain from producing such a high quantity of drugs that implementing proper quality control measures became difficult or impossible; and
- i. refrain from engaging in any other act or omission determined during the course of discovery.

72. The product methylprednisolone acetate administered to Mr. Wingate was not reasonably safe at the time it left the defendants' control.

73. At the time the product left the control of the defendants, a feasible and reasonably implementable alternative production practice was available that would have prevented the harm caused to Mr. Wingate without significantly impairing the usefulness or desirability of the product and without creating equal or greater risk of harm to others.

74. Mr. Wingate's death occurred as a direct and proximate result of the defendants' breaches of their duties to Mr. Wingate listed above.

COUNT III: STRICT LIABILITY

75. The plaintiff hereby incorporates each of the preceding paragraphs as if set out fully herein.

76. The defendants manufactured and sold a product that was inherently dangerous for any human use, particularly those involving introduction of the tainted drug into the central nervous system.

77. The inherently dangerous nature of the product was present at the time the product left the defendants' control.

78. Mr. Wingate's death was directly and proximately caused by the introduction of the defendants' inherently dangerous product into his body.

COUNT IV: NEGLIGENT FAILURE TO WARN

79. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

80. The defendants were aware that NECC's production quantities exceeded amounts in which they could properly implement necessary quality controls.

81. The defendants knew or had reason to know that the drug given to Mr. Wingate was not produced under conditions that could reasonably ensure quality and sterility.

82. On information and belief, the defendants chose not obtain independent sterility test results from a representative sampling of the applicable batch of this drug from a third party sterility testing facility as other compounding pharmacies do before releasing such drugs. The size of the batches at issue made any such sampling (if done) representative of the thousands of dosages created.

83. The defendants knew or had reason to know that compounding medications surrounded by the owner's garbage recycling center would result in increased chances of contaminating such drugs before and during the manufacturing process. These circumstances, while unreasonable and unbelievable under any scenario, further heightened the need to adhere to

strict safety, quality, sterility and testing protocols. But, none of this was done. As a result, it was not a matter of “if” adulterated drugs would be produced and sold by NECC, but instead, a matter of when such would occur or when it would occur to such an extent that illness or death resulted. NECC was engaged in what amounted to “Russian-Roulette” with its practices.

84. Because of their knowledge of those issues, as well as other things, the defendants knew or had reason to know that their product, the methylprednisolone acetate, was dangerous for its intended uses.

85. The defendants had no reason to believe that Mr. Wingate would realize the dangerous condition of the methylprednisolone acetate.

86. Mr. Wingate could not possibly have contemplated or anticipated the dangerousness of the defendants’ product, as it was contained in a single, unremarkable dosage vial.

87. By engaging in the acts and omissions described above, and by failing to inform the buyers and foreseeable users of the contamination of the methylprednisolone acetate, the defendants failed to exercise reasonable care to inform users of the dangers associated with the product’s use.

COUNT V: GROSS NEGLIGENCE

88. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

89. Each of the foregoing acts and omissions by the defendants went beyond mere thoughtlessness, inadvertence or error of judgment.

90. Such acts and omissions constituted such an utter disregard for the rights of others, and such an utter disregard for prudence, that they amount to complete neglect of the safety of others, including Mr. Wingate. The defendants’ acts and omissions were a heedless and palpable

violation of their legal duties respecting the life and rights of Mr. Wingate. Frazier v. City of Norfolk, 234 Va. 388, 393, 362 S.E.2d 688, 691 (1987).

91. Mr. Wingate's death occurred as a direct and proximate result of the defendants' grossly negligent acts and omissions.

COUNT VI: BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

92. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

93. The defendants had a duty to buyers and foreseeable users such as Mr. Wingate to provide a product that was not unreasonably dangerous for the use for which it was intended, and was not unreasonably dangerous for other foreseeable uses.

94. Despite that duty, the methylprednisolone acetate was unreasonably dangerous for the use for which it was intended—epidural injection into the bodies of patients, including Mr. Wingate—as well as other reasonably foreseeable uses.

95. The methylprednisolone acetate was unreasonably dangerous for the above-stated uses at the time the product left the defendants' hands.

96. The unreasonably dangerous condition of the methylprednisolone acetate directly and proximately caused Mr. Wingate's fungal meningitis and subsequent death.

**COUNT VII: BREACH OF IMPLIED
WARRANTY OF USE FOR A PARTICULAR PURPOSE**

97. The plaintiff hereby incorporates each of the preceding paragraphs as if set forth fully herein.

98. The defendants have heavily marketed both NECC itself and the product methylprednisolone acetate at medical trade shows and the like for use in the pain management setting, including but not limited to inclusion in epidural injections for back pain relief.

99. The defendants knew or had reason to know that the intermediate buyer, Insight Imaging, planned to use the methylprednisolone acetate in administering epidural injections to patients.

100. As such, the defendants knew or had reason to know the particular purpose for which the methylprednisolone acetate was purchased.

101. The defendants had reason to know that their skill or judgment was being relied upon to provide appropriate and reasonably safe goods.

102. At the time of the sale, the methylprednisolone acetate failed to satisfy the purpose contemplated at the time of sale—to be injected into the central nervous systems of patients such as Mr. Wingate without causing those patients to suffer unanticipated and unreasonably unsafe side-effects, e.g., fungal meningitis and death.

103. The failure of the product to satisfy the purpose contemplated at the time of sale proximately caused Mr. Wingate's fungal meningitis and death.

COUNT VIII: MEDICAL NEGLIGENCE
(defendant Cadden)

104. Plaintiff repeats and re-alleges all allegations contained in the preceding paragraphs as if they were fully set forth herein.

105. As director of pharmacy and licensed pharmacist in charge of NECC's operations, Cadden was at all relevant times acting as NECC's agent and / or principal.

106. Cadden had a duty to Mr. Wingate and other patients receiving these injections to utilize basic safety and cleanliness standards in the drug manufacturing processes.

107. Cadden had a duty to Mr. Wingate and other patients receiving these injections to exercise reasonable care to ensure that the drugs NECC manufactured were sterile and were not adulterated.

108. Cadden breached his duties to Mr. Wingate. He failed to utilize basic safety and cleanliness standards in the drug manufacturing processes, and he failed to exercise reasonable care to ensure that the drugs he and NECC manufactured were sterile and not adulterated.

109. Cadden's breaches of duty to Mr. Wingate proximately caused Mr. Wingate's death.

110. The plaintiff has incurred funeral, burial, and medical expenses, and Mr. Wingate's beneficiaries have suffered extreme mental anguish, sorrow, loss of companionship, comfort, guidance, kindly offices, invaluable services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes, as a proximate result of NECC's and Cadden's breaches of the duties they owed to Mr. Wingate. Va. Code § 8.01-50, *et seq.*

111. The Plaintiff certifies that she has complied with Va. Code § 8.01-50.1 before requesting service of process.

WHEREFORE, Sharon G. Wingate, Executor of the Estate of Douglas Gray Wingate, deceased, by counsel, moves this Court for judgment against the defendants, jointly and severally, in the amount of \$25,000,000 plus taxable costs with pre- and post-verdict interest on all of these amounts, as well as \$350,000 in punitive damages.

PLAINTIFF REQUESTS A TRIAL BY JURY ON ALL ISSUES.

SHARON G. WINGATE, EXECUTOR OF THE
ESTATE OF DOUGLAS GRAY WINGATE,
DECEASED,

/s/ J. Scott Sexton

By Counsel

J. Scott Sexton, Esq. (VSB No. 29284)
Anthony M. Russell (VSB No. 44505)
Charles H. Smith, III (VSB No. 32891)
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*Counsel for Sharon G. Wingate, Executor of the
Estate of Douglas Gray Wingate, deceased*



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EXHIBIT A

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Sharon G. Wingate, Executor of The Estate of Douglas Gray Wingate, deceased

(b) County of Residence of First Listed Plaintiff Salem

(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

J. Scott Sexton, Esq. / Geniry Locke Rakes & Moore, LLP
10 Franklin Road, SE, Suite 800, Roanoke, VA 24011 / 540-983-9300

DEFENDANTS

New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center, Medical Sales Management, Inc., Barry J. Cadden

County of Residence of First Listed Defendant

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | | | |
|---|--|---|--|
| Citizen of This State | PTF <input checked="" type="checkbox"/> 1 DEF <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | PTF <input type="checkbox"/> 4 DEF <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	PERSONAL PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	<input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 861 HIA (1395B) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	

V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Recopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. 1332(a) - Diversity

Brief description of cause:

Wrongful death caused by tainted steroid

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND \$ 25,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

11-20-12

SIGNATURE OF ATTORNEY OF RECORD

J. Scott Sexton

FOR OFFICE USE ONLY

RECEIPT #

0423-1663177

AMOUNT

350.00

APPLYING IFP

JUDGE Wilson

MAG. JUDGE

7:12-cv-00576